9. (Once amended.) [A] The system of claim [1] 8 where the electro-mechanical transducer is a longitudinal transducer.

10. (Once amended.) [A] The system of claim [1] 8 where the electro-mechanical transducer is a torsional transducer.

11. (Once amended.) [A] The system of claim 8 where said source of irrigation fluid also provides vacuum and is connected to said electro-mechanical transducer.

Remarks

The Applicant replies to the first official action of the United States Patent and Trademark Office of December 1, 2001 with three months to reply ending on March 1, 2002. Submitted with a preliminary amendment filed on June 17, 2001 was a power of attorney signed by the Applicant empowering the undersigned attorney and a change of correspondence address in the first action these changes were not acknowledged. The action was sent to the inventor. The Examiner's approval of the revised drawings is appreciated and that evidences that the mentioned power and address changes were received by the patent office.

Support for Applicant's amendments to the claims can be found in Applicant's figures wherein an angled arrow clearly illustrates the combined longitudinal and torsional motion of the resonator and in the ample discussions in the specification about the cited Boukhny reference. Boukhny is specifically referred to hereinafter in these remarks. The Mitskevich reference, (Sources of High Intensity Ultrasound, V. 2) that was background and extensively explained in the detailed description of the invention, as originally filed has no disclosure of treatment of biological tissue. Mitskevich clearly identifies the motional components of the combined LT resonators as each separately occurring at one frequency and explains the method of measurement for observing these components and the resultant single frequency motion (paragraph beginning on p. 175). Mitskevich shows the longitudinal and torsion components of one

particular resonator (Figure 23, p.175 and Fig. 28, p. 179). The torsional and longitudinal motions are components of one motion at one frequency. Mitskevich shows LT resonators and the single unique motion they produce, the motion having both a torsional and longitudinal component. Mitskevich further illustrates the measured direction and magnitude of this motion that always occurs at a single frequency.

Mitskevich, however, does not show Applicant's claimed LT resonators with tips shaped suitably for the removal of biological tissue, such as Applicant's knife-edges for cutting or hollow tubes for both cutting and aspirating tissue. Mitskevich's devices are described for use in the cutting of glass or the welding or drilling of metals. Mitskevich does not provide any suggestion that LT motion is useful in separating or removing biological tissue or that LT resonators may communicate the motion they generate to mechanically attached tips shaped for removal of biological tissue.

Applicant was the first to understand and apply the Mitskevich reference of the early 1970's. Even Boukhny's publication of 2001, fails to recognize the usefulness of combined longitudinal and torsional motion on difficult to remove biological tissue. Thus for over thirty years the Mitskevich teachings lay fallow proving that it was unobvious to make the claimed combination. In addition, Applicant's claimed system is being prepared for commercialization by the required efficacy testing in advance of introduction. Specifically, LT resonators with tips suitably shaped for the removal of biological tissue are currently being produced and tested under agreement with the Applicant by Mutoh America Corporation, 5 Commonwealth Road, Natick, MA 01760.

The dependency of claims 5 and 9 has in accord with the Examiner's comments been changed to 4 and 8 respectively in the amended and clean set of claims submitted herewith. The dependency of claims 6 and 10 has in accord with the Examiner's comments been revised to 4 and 8 respectively in the amended and clean set of claims submitted herewith. These amendments should overcome the Examiner's 35 USC 112 rejections.

The Examiner has rejected claims 1-3, 5, 6, 9 and 10 under 35 USC 102(e) as being anticipated by Boukhny, U.S. Patent 6,077,285. The Examiner states that '285 discloses an ultrasonic longitudinal-torsional system comprising an electrical generator (26), an electro-mechanical transducer (18, 20), a resonator (16) and a tip (12, 13).

Applicant has reviewed the '285 references and respectfully disagrees with the Examiner's assessment of the disclosure thereof as regards being anticipated by Boukhny. Boukhny discloses a transducer that is capable of providing longitudinal and torsional motion separately, but to do so Boukhny requires two separate generators and piezo-active sets of materials. Boukhny's exciting only one of his two transducers will produce only one type of motion, L or T. In Applicant's claimed system, exciting the electro-mechanical transducer produces combined LT motion in the tip connected to the LT resonator.

As repeatedly discussed in the present specification, one of the principal advantages of Applicant's claimed L-T resonator is simultaneous torsional and longitudinal motion using one electrical generator supplying alternating electrical voltage and current the transducer. Boukhny's device must operate a two different frequencies simultaneously, a fact which he clearly recognizes and states in the specification and abstract. Thus the motions, torsional and longitudinal, are not and can not be executed at the same frequency and do not constitute one motion but, rather, two.

Also, because in Boukhny's device, these motions are separate and occur at different frequencies the nodes of motion on the hand piece are located at different points. As a practical matter, which must concern anyone commercializing such surgical instruments, the devices are made useful for surgical purposes by positioning them within a stationary hand piece. The hand piece only remains essentially vibration free if the resonator is fastened or mounted to the hand piece at a node of motion that is stationary with respect to the hand piece. Mounting the resonator at the node assures that no resonance is transmitted to the surgeon's hand. Hence, if the fastening is made at nodes of longitudinal motion, then it will not be so fastened for torsional motion, and vice

versa as would be the result in Boukhny. This distinction is a very important practical matter, both for the surgical operator of the instrument and for minimizing the power lost in heat from friction in providing the motion. The expected result from two asynchronous simultaneous motions does not have the same efficiency, tissue dissection effect or efficacy as does one L-T motion.

Boukhny teaches only providing L and T motion at two different frequencies with two different sets of nodes, not Applicant's L-T motion at a single frequency with a unique set of L-T motional nodes. Applicant's single angled arrow depicts combined L-T motion. Such an arrow was not and could not be used to describe the motion provided by Boukhny as it has two separate, independent motions, one purely torsional and the other purely longitudinal, occurring at different frequencies.

The Examiner has rejected claims 4, 7, 8 and 11 under 35 USC 103(a) as being unpatentable over Boukhny, U.S. Patent 6,077,285 in view of Banko et al. U.S. Patent 3,589,363. The Examiner explains that, Banko et al. discloses using suction and irrigation in the same field of endeavor to aid in the removal of unwanted particles. The Examiner concludes that it would have been within the level of one skilled in the art to utilize irrigation and suction with the '285 device for the same advantages taught by '363.

Banko teaches irrigation and aspiration "I/A" and their simultaneously application with longitudinal ultrasonic motion, see '363 column 5, line 30; column 6, lines 10-20. Banko does not teach this combination for torsional and longitudinal motion executed in frequency synchronism as Applicant claims, nor does it teach the efficacious tissue dissection results that are obtained in combining irrigation, aspiration and L-T ultrasonic motion, an efficacy which Applicant's specification emphasizes.

Aside from the fact that Banko does not disclose I/A in combination with L-T vibration, the '363 patent clearly states that the device is intended for the removal of "...soft, yielding material....", in Column 1, lines 51-54. Hence Banko does not describe the removal of hard tissue such as bone or tissue, such a collageous tissue, that is resistant to vibration. Such tissue removal in

Applicant's specification is discussed as possible by using combined longitudinal and torsional vibration. It would not have been obvious that by changing the type of vibration in conjunction with I/A that such a result could be accomplished.

In addition to the absence of discussion of the limitations of longitudinal vibration in removing tissue in Banko's '363 patent, the Applicant's earlier Wuchinich et al in the '557 patent does not disclose the presently claimed invention. In '557, a device having I/A and enhanced longitudinal vibration is disclosed in Column 3, 10-12, for removal elastic tissue such neurologic tissue, and for which the Banko device and all predecessor devices as described therein are unsuitable in Column 1, 40 - Col. 2, 5. Notwithstanding the same inventor in '557 as herein, '557 does not discuss the further enhancement for hard tissue removal that is obtained with the use of the new and herein claimed combined L-T vibration with I/A.

The claims have been amended and distinguished over the cited references, reconsideration and allowance are respectfully requested.

On behalf of the Applicant, Wuchinich by his attorney,

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